UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,710	03/19/2004	George DeStefano	09-0277	7531

28509 7590 10/16/2009

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM USA CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
10/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/804,710	DESTEFANO ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/28/09 has been entered.

Receipt is acknowledged of the Remarks filed on 07/28/09. Claim 12 has been added while no claims have been amended or cancelled. Accordingly, claims **1-2 and 4-12** are pending.

Claim Rejections - 35 USC § 112

Claim 12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specification does not contain any support for the specific range of 0.15 to 0.18%. Applicant has referred to pages 1 and 3 as containing support for the amendments, however only range recited in the specification is 0.13 to 0.18%. This is a new matter rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al (US 6,261,539).

Adjei et al teach medicinal formulations containing a particulate drug, a propellant and a stabilizing agent comprising a water addition (see abstract and col. 2, lines 42-45). Suitable medicaments include albuterol and ipratropium bromide (see col. 2, lines 54-58). Suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 32-45). Suitable stabilizer is a water addition (see col. 3, line 47-58). It is also disclosed that generally the formulation comprises about 300 ppm after and an amount of from 300 to 2000 ppm water is added as a stabilizer (col. 4, lines 8-20 and claim 7). Suitable co-

solvent is **ethanol** (see col. 2, lines 30-33). Conventional lubricants, surfactants and co-solvents can be added (col. 4, lines 34-38).

Adjei also discloses that "An aerosol formulation preferably comprises the water ;addition **in an amount effective to stabilize the formulation** relative to an identical formulation not containing the water addition i.e. containing only nascent formulation water, such that the drug does not settle, cream or flocculate after agitation so quickly as to prevent **reproducible dosing** of the drug (see col. 3, lines 59-65). Adjei further discloses that the water addition must be present in a formulation in an amount in excess of the concentration of the nascent formulation water (see col. 4, lines 8-29).

While Adjei does not anticipate the claimed formulation because the specific range of water is not disclosed, Adjei teaches the same formulations and that addition of a small amount of water to the formulations provides stability to the formulations. The water is added as a stabilizer. The claimed concentration range of 0.13 to 0.18% is within the disclosed range of 0.03 to 0.2% (300 to 2000 ppm). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the suitable amount of water as disclosed by Adjei according to the active agent and other excipients in the formulation. Thus, regarding the claimed ranges, it is considered that where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See MPEP 2144.05 [R-5].

It has also been decided that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

Claims 1-2, 4, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (EP 1219293).

Lewis et al teach a composition for use in an aerosol inhaler comprising an active agent, an HFA propellant and a cosolvent. Cosolvents include alcohols such as **ethanol** and propellants include HFA 134a and HFA 227 (see [0012] and [0010]). The active agents may be any one or more salbutamol (also known as albuterol), ipratropium bromide, beclomethasone, etc (see [0064]). The formulations may include a low volatility component such as **polyvinyl pyrolidone** (see 0056]). Other suitable low volatility materials include saturated and unsaturated carboxylic acids such as ascorbic acid (see [0055]).

Lewis also discloses the method of making the formulation and filling the aerosol inhaler. The method includes filling the container with a) one or more active materials, b) One or more low volatility components, c) One or more co-solvents followed by the addition of the HFA propellant. The formulations are said to contain up to 0.5% water and Table 2, discloses four formulations two of which contain **0.1% water**.

While Lewis et al does not anticipate the claimed formulation because the specific range of water is not disclosed, Lewis et al teach the same formulations and that addition of a small amount of water to the formulations provides stability to the formulations. Lewis et al teach the broader range of up to 0.5% and exemplify formulations that contain 0.1%. The cited "0.1%" by Lewis et al could potentially be the rounded amount of 0.1 to <0.2%, which includes 0.13 to 0.18%. Even if this is not the interpretation given to the disclosure, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the suitable amount of water as disclosed by Lewis et al according to the active agent and other excipients in the formulation. Thus, regarding the claimed ranges, it is considered that where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See MPEP 2144.05 [R-5].

It has also been decided that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of

scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

Claims 1-2, 4, 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,511,652).

Ashurst et al teach a metered dose inhaler having part or all of its internal surfaces coated with one or more fluorocarbon polymers for dispensing an inhalation drug formulation comprising beclomethasone dipropionate, a propellant in combination with other active agents and one or more excipients (see abstract and summary). The co-solvent is preferably an alcohol such as **ethanol** (col. 2, lines 60-66). Suitable active agents include **salbutamol, ipratropium**, etc or combinations thereof. Suitable propellants include **HFA 134a or HFA 227** (col. 3, lines 5-50).

Ashurst et al also discloses that the said formulation preferably contain at least 0.015%, e.g. 0.015 to 0.1% water by weight of the formulation (col. 5, lines 24-39).

While Ashurst et al does not anticipate the claimed formulation because the specific range of water is not disclosed, Ashurst et al teach the same formulations and the addition of a small amount of water to the formulations. Ashurst et al teach the broader range of at least 0.015% and exemplify formulations that contain 0.015 to 0.1%. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the suitable amount of water as disclosed by Ashurst et al according to the active agent and other excipients in the formulation. Thus, regarding the claimed ranges, it is considered that where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See MPEP 2144.05 [R-5].

It has also been decided that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

Claims 1-2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Keller et al (6,475,467).

Keller et al teach suspension formulations for delivery by metered dose inhalers comprising active agents in particulate form. It is disclosed that in such formulations the amount of **water** is less than 1% by weight (see col. 3, lines 55-67). The active agents suitable for the said formulations include ipratropium bromide, salmeterol, mometasone, etc. Formulations may comprise **two or more active agents** (col. 5, lines 20-45). Examples of preferred co-solvents include **ethanol** (col. 9, lines 1-10). Formulations may contain a buffer substance such as **citric acid** (col. 9, lines 29-35). Suitable propellants include HFA 134a and HFA 227 (col. 7, lines 54-60).

Keller et al does not anticipate the claimed formulation because the specific range of water is not disclosed, however, Keller et al's formulation comprise less than 1% water. While the range of less than 1% is a broader range compared to the specific range of 0.13 to 0.18% as claimed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the suitable amount of water as disclosed by Keller et al according to the active agent and other excipients in the formulation. Thus, regarding the claimed ranges, it is considered that where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See MPEP 2144.05 [R-5].

It has also been decided that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

Claims 5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al in view of Jager et al (WO 9413262).

Adjei et al, discussed above, lacks specific disclosure on addition of citric acid.

Jager et al teach stabilized medicinal aerosol solution formulations comprising medicaments that degrade or decompose by interaction with solvents or water, an HFC propellant, a cosolvent and an acid (see abstract). Most preferred medicaments for use in the said aerosol solution formulations include **ipratropium bromide and albuterol** (see page 8, lines 3-8). The suitable cosolvents include ethyl alcohol, polyethylene glycol, glycerol, etc. Most preferred cosolvent is **ethanol** (see page 9, line 17 to col. 10, line 11). The disclosed formulations contain an acid to prevent degradation. Suitable acids include ascorbic acid and **citric acid**, and the most preferred acid is citric acid

(page 10, lines 17-32). Table 1 discloses a formulation comprising ipratropium bromide monohydrate, ethanol, HFA 134a, acid and water in the amount of 0.0 to 5%.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined formulations and method of making them as taught by Adjei et al and Jager et al and end up with the claimed formulations. Alternatively, it would have been obvious to one of ordinary skill in the art given the general teachings of Adjei et al on the formulations, to have looked in the art for other suitable excipeints such as stabilizers like, citric acid as taught by Jager et al with the reasonable expectations of successfully preparing stable and effective formulations for aerosol administration. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (EP 1219293) in view of Jager et al (WO 9413262).

Lewis et al and Jager et al are discussed above. Lewis et al discloses all the components of the instant claims except for citric acid. While disclosing addition of carboxylic acids such as ascorbic acid, lacks specific disclosure on citric acid.

Jager et al teaches the addition of an acid such as citric acid to the formulations as a stabilizer and a buffer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined formulations and method of making them as taught by Lewis et al and Jager et al and end up with the claims formulations. Alternatively, it would have been obvious to one of ordinary skill in the art given the general teachings of Lewis et al on the formulations and method of making them, to have looked in the art for specific carboxylic acids such as citric acid as taught by Jager et al with the reasonable expectations of successfully preparing stable and effective formulations for aerosol administration. In other words, the claims would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-2, 4-12** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,423,298 in view of Adjei et al (US 6,261,539). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant Application would have been obvious over the claims of the U.S. Patent '298 in view of Adjei et al '539. Specifically, the instant claims and the reference claims are drawn to a formulation comprising an HFA propellant, one or more active agents and one or more excipients. The instant claims additionally require 0.13 to 0.18% water and reference claims do not require water. Adjei et al discloses similar formulations and teaches that the addition of a small amount of water from 300 to 2000 ppm, would improve stability of the formulations. Thus it would have been obvious to one of ordinary skill in the art to have implemented the teachings of Adjei e et al on water addition, as a stabilizer in the formulations of the reference claims with a reasonable success.

Response to Arguments

Applicant's arguments filed 07/28/09 have been fully considered but they are not persuasive.

Applicant's main argument appears to be that none of the references applied in the rejection of instant claims teach the specific water concentration range of 0.13 to 0.18%. Applicant then concludes that none of the references can properly anticipate the narrow range of the instant claims. Applicant also argues that Adjei does not teach a combination of albuterol and ipratropium.

With regard to the specific amount of water, the argument is not persuasive because while Adjei, Lewis or Ashurst references do not teach the specific range of 0.13 to 0.18% water, they each have a slightly broader range and they all recognize that the small amount of water is advantageous in stability of the formulation and the reproducibility of the actuations. Adjei also teaches that the water should be added in an amount effective to stabilize the formulation and to prevent settling or creaming so that reproducibility of dosing is not affected.

With regard to the combination of drugs, while this is correct, the argument is not persuasive because Adjei teaches the medicament can be any of the actives suitable for inhalation such as albuterol and iprtropium bromide. Adjei also claims a combination of medicaments for example in claims 5 and 12. Thus it would have been obvious to one of ordinary skill in the art to have combined the medicaments as needed for the treatments. Furthermore, Adjei does not link the need to stabilize the formulation with a specific amount of water addition to any particular active agent, thus one of ordinary skill in the art would have been motivated to apply the teachings to any active agent or combinations thereof.

Applicants further argue that Examiner has not interpreted the data in the Declaration of George DeStefano properly. Applicants state that Examiner has incorrectly compared the amount of active ingredients present in one actuation event from three cans, each can having a different water content. Applicants state that "Examiner should compare, as applicants have previously done to show the unexpected results, reproducibility in a single "can" containing a specific water content (i.e. 2500 ppm) to repeatedly provide the same amount of the active ingredients released from the same "can" over a series of single actuation events as compared to a "can" containing a different water content (i.e. 1500 ppm)". Applicants state that "The first eight tables in Report No. AS/C-03004 (submitted in the DeStefano declaration), show that the SAR of albuterol sulfate is very inconsistent between actuation events in cans containing a water content level ranging from inherent (approximately 300 ppm) to 1200 ppm" (see Remarks, page 5).

The arguments are not persuasive, 1) because the argued preferred range is within the range of prior art such as Adjei (300-2000 ppm) and Lewis et al (up to 0.5% and examples of 0.1%). Also Adjei specifically teaches adding the said amount of water as a stabilizer for the formulation and to prevent problems with reproducibility of dosing. That is exactly what Applicants are claiming they have discovered. 2) Applicant's arguments regarding better results when water content is from 0.13 to 0.18% (the specific range) is not found persuasive. Interpreting the data as the Applicant has requested shows that in certain water content levels, the actuations are more consistent than in others, however it is not adequate to support the claimed range.

Firstly, Applicants specification only exemplifies adding water at 0.13% and 0.17%. However the Declaration does not have any data for the 1300 and 1700 ppm. Secondly, the data shows that fluctuations in actuations for an inherent water content (300 ppm) is much higher than the cans that had water added. This was already disclosed by Adjei et al. In column 4, lines 13-20, Adjei et al discloses that inherent amount of water is about 300 ppm and that an amount of from 300 to 2000 ppm should be added to the inherent amount for improved stability and reproducibility of dosing. Thirdly, comparing the data for Cans containing 1200 ppm (not desirable) and 4000 ppm (desirable) shows that the fluctuations are similar. In the Can containing 1200 ppm water the fluctuations are from 85.73 to 138.10. In the Can containing 4000 ppm, the fluctuations are from 74.83 to 116.7. Even in the Can containing 1500 ppm of water, which is in the claimed range, the fluctuations are from 99.24 to 122.24. Thus Applicant has not shown any consistency with their data that supports the claimed range or unexpected results over the prior art's teaching.

Claims 1-2, 4-12are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616